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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,163	05/21/1999	WILHELM SCHWAEBLE	3523-P-002	7467

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EXAMINER
DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/316,163	Applicant(s) SCHWAEBLE ET AL.	
	Examiner DiBrino Marianne	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/18/02, 11/21/02 & 9/24/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5-8 and 11-36* is/are pending in the application.

4a) Of the above claim(s) *5-8,11-16,29 and 33-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,17-28,30-32 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

~~a)~~☐ All b)☐ ~~Some * c)~~☒ ~~None~~ of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The request filed on 6/18/02 (Paper No. 16) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/316,163 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's amendments filed 11/21/02 (Paper No. 21) and 9/24/02 (Paper No. 18) are acknowledged and have been entered.

Claims 2, 5-8 and 11-36 are pending.

3. Newly submitted claims 33-35, and 29 directed to inventions that are independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claims 33-35 are drawn to nucleic acid molecules which are classified in Class 536, subclass 23.5, which belong to nonelected group IV, as enunciated in the restriction requirement mailed 3/15/00. The instant invention is drawn to a molecule comprising complement control modules recited in the instant claims, however, newly submitted claim 29 is directed to a molecule comprising complement control modules that are dimers or trimers rather than monomers.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-35 and 29 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 5-8 and 11-16 remain withdrawn withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 2, 17-28,30-32 and 36 are currently being examined.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22-25, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

Applicant points to support on pages 4, 5, 9 and 26-32 (there are no pages 26-32 in the instant specification) as enunciated on page 4 of the said amendment filed 9/24/02, however, the disclosure is to inhibition of complement activation on page 4 of the instant specification.

b. The amendatory material that is not supported by the specification and claims as originally filed is as follows: "only 1-4, 1-5, and 1-6" recited in line 2 of claim 22.

The Examiner does not find support for the amendatory material in the disclosure pointed to by Applicant.

c. The amendatory material that is not supported by the specification and claims as originally filed is as follows: "have a sequence of 207 amino acids" recited in line 2 of claim 31.

The Examiner does not find support for the amendatory material in the disclosure pointed to by Applicant.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 17-21, 26-28, 31 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by pir62 Accession No. S03013 (previously provided) as evidenced by Ripoche et al (Applicant's IDS reference "A").

Pir62 Accession No. S03013 teaches a molecule *comprising* complement control protein modules 1-4 of human complement factor H *having* the sequence of SEQ ID NO: 9 of the instant application. Note that the claimed recitation of intended use in inhibiting complement activation in instant claims 20 and 24 does not carry any patentable weight per se. A compound is the same compound irrespective of its intended use.

With regard to claims 26-28 and 31 Ripoche et al teach forms of human factor H which are truncated at the C-terminus with relation to the 155 Mr form, including ones which are 45 Mr and 36 Mr (especially page 601 at column 2). Claims 26 and 27 recite Fhp43 and claim 28 recites "C-terminal deletions of about 180 amino

acids" and "sequence of 207 amino acids". With regard to claim 31, SEQ ID NO: 9 of the instant application is 207 amino acid residues in length.

With regard to instant claims 21 and 25, the property of having an enhanced efficacy when compared to Fhp155 is considered an inherent property of the reference compound. The claimed molecule appears to be the same as the art absent a showing of any differences. Since the Patent Office does not have the facilities for examining and comparing the molecule of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant's arguments in the amendment filed 9/24/02 have been fully considered but they are not persuasive.

It is Applicant's position (beginning on page 8) that the art reference teaches the entire sequence of human complement factor H, that there is no indication of which amino acid residues correspond to complement control protein modules or what those modules might be, where one ends and another begins, nor is there disclosure of complement inhibiting activity, nor constructs having CCP modules of factor H.

It is the Examiner's position that SEQ ID NO: 9 is SCR 1-4 (module 1-4) of human complement factor H protein, and that the claim language encompasses molecules that comprise SEQ ID NO: 9. The art reference teaches a molecule comprising SEQ ID NO: 9 of the instant application, and that sequence is 449 amino acid residues in length. It is not necessary that the art reference teach which amino acid residues correspond to complement control protein modules or what those modules might be, where one ends and another begins, nor constructs having CCP modules of factor H. Complement inhibiting activity is an inherent property of the claimed peptide.

8. Claims 2, 17-21, 26-28, 31 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by pir65 Accession No. S00254 (Dec. 31, 1993, previously provided) as evidenced by Ripoche et al (Applicant's IDS reference "A"). .

pir65 Accession No. S00254 teaches a molecule *comprising* complement control protein modules 1-4 of human complement factor H *having* the sequence of SEQ ID NO: 9 of the instant application. Note that the claimed recitation of intended use in inhibiting complement activation in instant claims 20 and 24 does not carry any patentable weight per se. A compound is the same compound irrespective of its intended use.

With regard to claims 26-28 and 31 Ripoche et al teach forms of human factor H, including the Mr 155 form as well as forms which are truncated at the C-terminus with relation to the 155 Mr form, such as those that are 45 Mr and 36 Mr (especially page 601 at column 2). Claims 26 and 27 recite Fhp43 and claim 28 recites "C-terminal deletions of about 180 amino acids" and "sequence of 207 amino acids". With regard to claim 31, SEQ ID NO: 9 of the instant application is 207 amino acid residues in length.

With regard to instant claims 21 and 25, the property of having an enhanced efficacy when compared to Fhp155 is considered an inherent property of the reference compound. The claimed molecule appears to be the same as the art absent a showing of any differences. Since the Patent Office does not have the facilities for examining and comparing the molecule of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant's arguments in the amendment filed 9/24/02 have been fully considered but they are not persuasive.

It is Applicant's position (beginning on page 8) that the art reference teaches the entire sequence of human complement factor H, that there is no indication of which amino acid residues correspond to complement control protein modules or what those modules might be, where one ends and another begins, nor is there disclosure of complement inhibiting activity, nor constructs having CCP modules of factor H.

It is the Examiner's position that SEQ ID NO: 9 is SCR 1-4 (module 1-4) of human complement factor H protein, and that the claim language encompasses molecules that comprise SEQ ID NO: 9. The art reference teaches a molecule comprising SEQ ID NO: 9 of the instant application, and that sequence is 449 amino acid residues in length. It is not necessary that the art reference teach which amino acid residues correspond to complement control protein modules or what those modules might be, where one ends and another begins, nor constructs having CCP modules of factor H. Complement inhibiting activity is an inherent property of the claimed peptide.

9. Claims 2, 17-21, 26-28, 30, 31 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Ripoche et al (Applicant's IDS reference "A") as evidenced by pir65 Accession No. S00254 and pir62 Accession No. S03013.

Ripoche et al teach forms of human factor H which are truncated at the C-terminus with relation to the 155 Mr form, including ones which are 45 Mr and 36 Mr (especially page 601 at column 2). Claims 26 and 27 recite Fhp43 and claim 28 recites "C-terminal deletions of about 180 amino acids" and "sequence of 207 amino acids". With regard to claim 31, SEQ ID NO: 9 of the instant application is 207 amino acid residues in length. With regard to claim 30, Ripoche et al further teach factor H coupled to a chromatographic medium, i.e., an "artificial membrane". With regard to instant claim 30, the recitation of a method wherein the claimed product is made, i.e., how it is coupled, carries no patentable weight in these product claims.

pir65 Accession No. S00254 and pir62 Accession No. S03013 have been discussed supra.

With regard to instant claims 21 and 25, the property of having an enhanced efficacy when compared to Fhp155 is considered an inherent property of the reference compound. The claimed molecule appears to be the same as the art absent a showing of any differences. Since the Patent Office does not have the facilities for examining and comparing the molecule of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant's arguments in the amendment filed 9/24/02 have been fully considered but they are not persuasive.

The Examiner's arguments supra apply herein.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The examiner can normally be reached on Monday and Thursday from 11 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
March 17, 2003

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
3/21/03